

Amendments to the Claims

Kindly amend the claims as follows:

Claim 1. (Currently Amended) A cervical cap comprising:

a rim member dimensioned to snugly fit a patient's exocervix;

a cap dome extending from [[the]] said rim member to cover the exocervix and having an opening to allow fluid flow out of [[the]] said cap dome, [[the]] said cap dome being custom-molded to substantially completely conform to the shape of ~~the patient's cervix~~ said exocervix; and

a valve associated with [[the]] said opening, constructed to allow outflow while preventing flow into said cap dome.

Claim 2. (Currently Amended) The cervical cap of claim 1, wherein [[the]] said valve comprises a check valve sealingly positioned in said opening.

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Claim 3. (Currently Amended) The cervical cap of claim 1, wherein [[the]] said valve comprises a membrane disposed over an outer surface of [[the]] said dome and sealed to [[the]] said cap dome in spaced regions.

Claim 4. (Cancelled)

Claim 5. (Currently Amended) The cervical cap of claim 2, wherein [[the]] said check valve is a duckbill valve.

Claim 6. (Currently Amended) The cervical cap of claim 1, wherein [[the]] said valve comprises a collapsed tube valve.

Claim 7. (Cancelled)

Claim 8. (Currently Amended) The cervical cap of claim 3, wherein [[the]] said membrane has a thickness of less than 0.5 mm.

Claim 9. (Currently Amended) The cervical cap of claim 8, wherein ~~[[the]]~~ said membrane has a thickness of less than 0.25 mm.

Claim 10. (Currently Amended) The cervical cap of claim 3, wherein ~~[[the]]~~ said membrane comprises a silicone polymer.

Claim 11 (Currently Amended) The cervical cap of claim 1, wherein ~~the rim includes~~ said rim member comprises circumferential ridges on its inner surface.

Claim 12. (Currently Amended) The cervical cap of claim 1, said cap further comprising a portion that is impregnated or coated with a therapeutic agent and that is constructed to slowly release ~~[[the]]~~ said therapeutic agent during use of ~~[[the]]~~ said cap.

Claim 13. (Currently Amended) The cervical cap of claim 12, wherein said portion is removable.

Claim 14. (Currently Amended) The cervical cap of claim 13, wherein said portion is a removable ring that is press-fit onto the cap adjacent ~~[[the]]~~ said rim member.

Claim 15. (Currently Amended) The cervical cap of claim 12, wherein ~~[[the]]~~ said therapeutic agent is selected from the group consisting of microbicides, spermicides, medications, and combinations thereof.

Claim 16. (Currently Amended) The cervical cap of claim 12, wherein ~~[[the]]~~ said therapeutic agent is an iodine complex.

Claim 17. (Currently Amended) A cervical cap comprising (a) a cap body that is constructed to cover ~~[[the]]~~ a patient's exocervix and prevent ingress of sperm and fluids and ~~includes~~ comprises a cap dome that is custom-molded to substantially completely conform to the shape of ~~the patient's cervix~~ said exocervix, (b) a rim member, dimensioned to snugly fit ~~a patient's~~ said exocervix, from which the cap body extends, and (c) a portion, associated with ~~[[the]]~~ said cap

body, that is impregnated or coated with a therapeutic agent and is constructed to release [[the]] said therapeutic agent over a period of time during use of [[the]] said cap.

Claim 18. (Cancelled)

Claim 19. (Currently Amended) The cervical cap of claim 17, wherein said portion comprises a removable ring that is press-fit onto [[the]] said cap adjacent [[the]] said rim member.

Claim 20. (Currently Amended) The cervical cap of claim 17, wherein [[the]] said therapeutic agent is selected from the group consisting of microbicides, spermicides, medications, and combinations thereof.

Claim 21. (Currently Amended) The cervical cap of claim 17, wherein [[the]] said therapeutic agent is an iodine complex.

Claim 22. (Currently Amended) The cervical cap of claim 17, wherein [[the]] said therapeutic agent functions as both a spermicide and a microbicide.

Claim 23. (Currently Amended) A method of protecting the exocervix of a female, comprising applying to [[the]] said exocervix a custom-molded cervical cap comprising (a) a cap body ~~that includes~~ comprising a cap dome that is custom-molded to substantially completely conform to the shape of ~~the patient's cervix~~ said exocervix[[,]] and is constructed to cover [[the]] said exocervix and prevent ingress of sperm and fluids, (b) a rim member dimensioned to snugly fit ~~a patient's~~ said exocervix, and (c) a portion that is impregnated or coated with a therapeutic agent, [[the]] said portion being constructed to slowly release [[the]] said therapeutic agent during use of [[the]] said cap.

Claim 24. (Currently Amended) The method of claim 23, said method further comprising applying [[the]] said portion to [[the]] said cervical cap so that [[it]] said portion ~~will be~~ is removable and replaceable.

Claim 25. (Currently Amended) The method of claim 24, said method further comprising instructing ~~[[the]]~~ said female as to when ~~[[the]]~~ said removable portion should be replaced.

Claim 26. (Currently Amended) The method of claim 24, wherein ~~[[the]]~~ said portion comprises a removable ring and ~~[[the]]~~ said method further comprises press-fitting ~~[[the]]~~ said ring onto an outer surface of ~~[[the]]~~ said cervical cap.

Claim 27. (Currently Amended) The method of claim 23, wherein ~~[[the]]~~ said therapeutic agent is selected from the group consisting of microbicides, spermicides, medications, and combinations thereof.

Claim 28. (Currently Amended) A method of measuring the diameter of an exocervix of a patient comprising the steps of:

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- (a) providing a ring gauge comprising a plurality of ring members having different diameters ~~[[,]]~~ and means for positioning a selected ring member ~~[[on the]]~~ onto said patient's exocervix;
  - (b) inserting ~~[[the]]~~ said ring gauge ~~|, with one of the ring members, having a first diameter attached thereto,~~ into the vagina of ~~[[the]]~~ said patient;
  - (c) positioning ~~[[the]]~~ one of said ring members around ~~[[the]]~~ said patient's exocervix and determining whether ~~[[the]]~~ said selected rim member fits ~~[[the]]~~ said exocervix; and
  - (d) repeating steps (a)-(c) with ring members having different diameters until ~~[[a]]~~ said selected ring member ~~|is chosen which|~~ fits ~~[[the]]~~ said exocervix, with the diameter of ~~[[this]]~~ said selected ring member corresponding to the diameter of ~~|the patient's|~~ said exocervix.

Claim 29. (Currently Amended) ~~[[A]]~~ The method of claim 28, wherein said positioning means comprises a pair of elongated members adapted to be removably and rotatably attached to ~~[[the]]~~ one of said ring members.

Claim 30. (Currently Amended) ~~[[A]]~~ The method of claim 28, wherein ~~[[the]]~~ said gauge further ~~|includes a measuring means for measuring the depth of the exocervix,~~ comprises means for measuring and said method further ~~|includes|~~ comprises the step of (e) positioning ~~[[the]]~~ said measuring means to determine the depth of ~~[[the]]~~ said exocervix.

Claim 31. (Currently Amended) [[A]] The method of claim 30, wherein [[the]] said positioning means comprises a pair of elongated members adapted to be removably and rotatably attached to [[the]] one of said ring members and [[the]] said measuring means comprises a measuring member movably mounted on one of [[the]] said elongated members.

Claim 32. (Currently Amended) [[A]] The method of claim 28, said method further comprising the steps of , prior to inserting [[the]] said ring gauge:

- (a) inserting a cervical plunger[[,]] ~~|having|~~ comprising a plunger member and a tube member in fluid communication with [[the]] said plunger member;
- (b) placing [[the]] said cervical plunger on [[the]] said exocervix;
- (c ) drawing a vacuum through [[the]] said tube member to draw [[the]] said exocervix against an inner surface of [[the]] said plunger member; and
- (d) positioning ~~|the cervix|~~ said exocervix by moving the tube member.

Claim 33. (Currently Amended) A kit for use by a clinician in forming a custom cervical cap in situ[[,]] in a patient's body, comprising ~~|in combination|~~ a rim member dimensioned to fit an exocervix, [[the]] said rim member including a substantially ring-shaped surface that, when [[the]] said rim member is placed on ~~|the cervix|~~ said exocervix, faces toward the opening of the patient's vagina[[,]]; a curable material[[,]]; and [[a]] means for applying [[the]] said curable material.

Claim 34. (Currently Amended) A kit for use by a clinician in forming a custom cervical cap in situ[[,]] in a patient's body, comprising ~~|in combination|~~ a rim member dimensioned to fit an exocervix, a shell member dimensioned to be mounted on said rim member, a curable material, and [[a]] means for applying [[the]] said curable material.

Claim 35. (Currently Amended) [[A]] The kit of claim 34, wherein [[the]] said shell member has an aperture.

Claim 36. (Currently Amended) [[A]] The kit of claim 34, wherein [[the]] said shell member has at least one tube.

Claims 37-38. (Cancelled)

Claim 39. (Currently Amended) [[A]] The kit of claim 34, said kit further comprising a cervical plunger.

Claim 40. (Currently Amended) [[A]] The kit of claim 35, said kit further comprising a cervical plunger.

Claim 41. (Currently Amended) The cervical cap of claim 17, said cap further comprising a valve constructed to allow outflow from [[the]] said cap body while preventing fluid flow into said cap body.

Claim 42. (Currently Amended) The cervical cap of claim 41, wherein said valve is selected from the group consisting of check valves and collapsed tube valves.

Claim 43. (Currently Amended) The cervical cap of claim 41, wherein said valve comprises a membrane disposed over an outer surface of [[the]] said cap body.

Claim 44. (Currently Amended) The cervical cap of claim 2, wherein [[the]] said valve further comprises a collapsed tube valve.

Claim 45. (Currently Amended) The cervical cap of claim 1, wherein [[the]] said cap dome comprises a cured polymeric material.

Claim 46. (Currently Amended) The cervical cap of claim 1, wherein said portion is removable.

Claim 47. (Currently Amended) The cervical cap of claim 17, wherein said portion is replaceable.

Claim 48. (Currently Amended) The cervical cap of claim 47, wherein said portion is removable.

Claim 49. (Currently Amended) The kit of claim 33, said kit further comprising a ring gauge.

Claim 50. (Currently Amended) The kit of claim 34, said kit further comprising a ring gauge.

Claims 51-56. (Cancelled)

Claim 57. (Currently Amended) A kit for use by a clinician in forming a custom cervical cap in situ[[,]] in a patient's body[[,]] comprising ~~in combination~~ a rim member dimensioned to fit an exocervix, a ring gauge, a curable material, and [[a]] means for applying [[the]] said curable material.

Claim 58. (Currently Amended) A cervical cap comprising[[,:]] a snugly fitting rim member dimensioned to fit a patient's exocervix and a cap dome[[,]] bonded to [[the]] said rim member, wherein [[the]] said cap dome [[being]] is custom-molded to substantially completely conform to the shape of ~~the patient's cervix~~ said exocervix.

Claim 59. (Currently Amended) The cervical cap of claim 58, wherein [[the]] said rim member comprises one or more ridges configured to securely grip [[the]] said exocervix.

Claim 60. (new) The cervical cap of claim 1, wherein said rim member and said cap dome are of different chemical compositions.

Claim 61. (new) The cervical cap of claim 60, wherein said rim member comprises MED 54220 silicone or MED 4860 silicone and said dome comprises SILASTIC 382 silicone or MED 64220 silicone.